

OCT 22 1998

K982580

510(K) SUMMARY

Bird Monitor Interface

Bird Products Corporation

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July 21, 1998

General Information

Device Trade Name: **Bird Monitor Interface**

Device Common/Classification Name:

The Bird Monitor Interface is an *accessory* to Bird Products Corporation ventilator products classified under 73 CBK "Continuous Ventilators"

Predicate Device: **Bird RS-232 Interface Module**
 FDA 510(k) No: K880721

Option 20-26 of Puritan Bennett 7200 Volume Ventilator
FDA 510(k) No: K841757

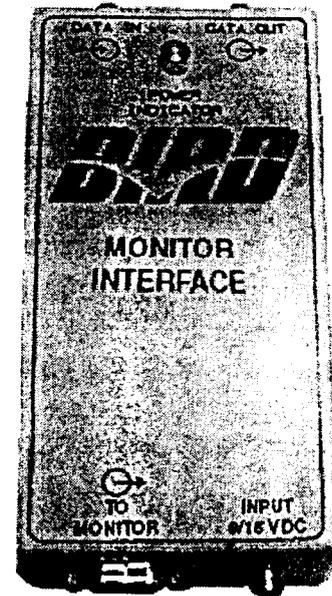
Intended Use:

The Bird Monitor Interface (BMI) is a stand-alone unit providing a means of communicating information from Bird ventilators to patient monitoring systems. Specific interfaces to the Hewlett-Packard Merlin and SpaceLab's PDMS are provided, as well as a Bird proprietary interface for use with other systems. The purpose of BMI is to deliver ventilator settings, monitored values, alarm information and waveform data to the patient monitoring system.

Device Description

The Bird Monitoring Interface (BMI) is a stand-alone unit providing a communications interface between the Bird ventilators, 8400STi, VIP and TBird, and patient monitoring systems. Specific interfaces to the Hewlett-Packard Merlin (via Hewlett-Packard's Vuelink proprietary interface) and SpaceLab's PDMS (via Spacelab's Universal Flexport proprietary interface) are provided as well as a Bird proprietary interface, the General Purpose Computer Protocol (GPCP), for use with other systems. The purpose of the BMI is to deliver ventilator settings, monitored values, alarm information and waveform data to the patient monitoring system.

The BMI has no user-operated controls or displays. This device is activated when it is attached to a 9 to 15 Volt power supply and fully functional when attached to the ventilator and patient monitoring system. Indicators are limited to a power indicator.



The BMI is installed between the ventilator and the Patient Monitoring System. Figure 3-1 illustrates a typical BMI installation. Connection between the ventilator and the BMI is Fiber Optic. Connection between the BMI and the Patient Monitoring System is RS-232 compatible. The BMI also contains a fiber optic feed-through for connection to Bird accessories, particularly the Bird Graphics Monitor and The Partner Volume Monitor.

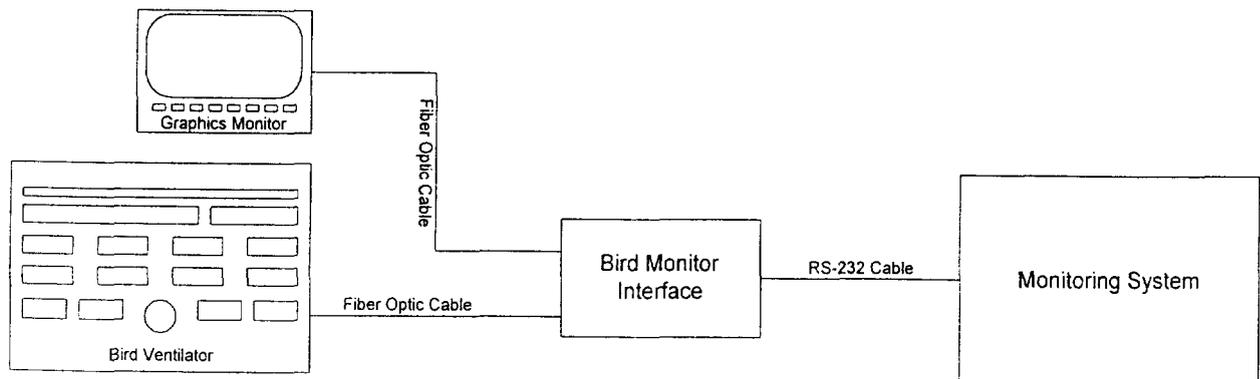
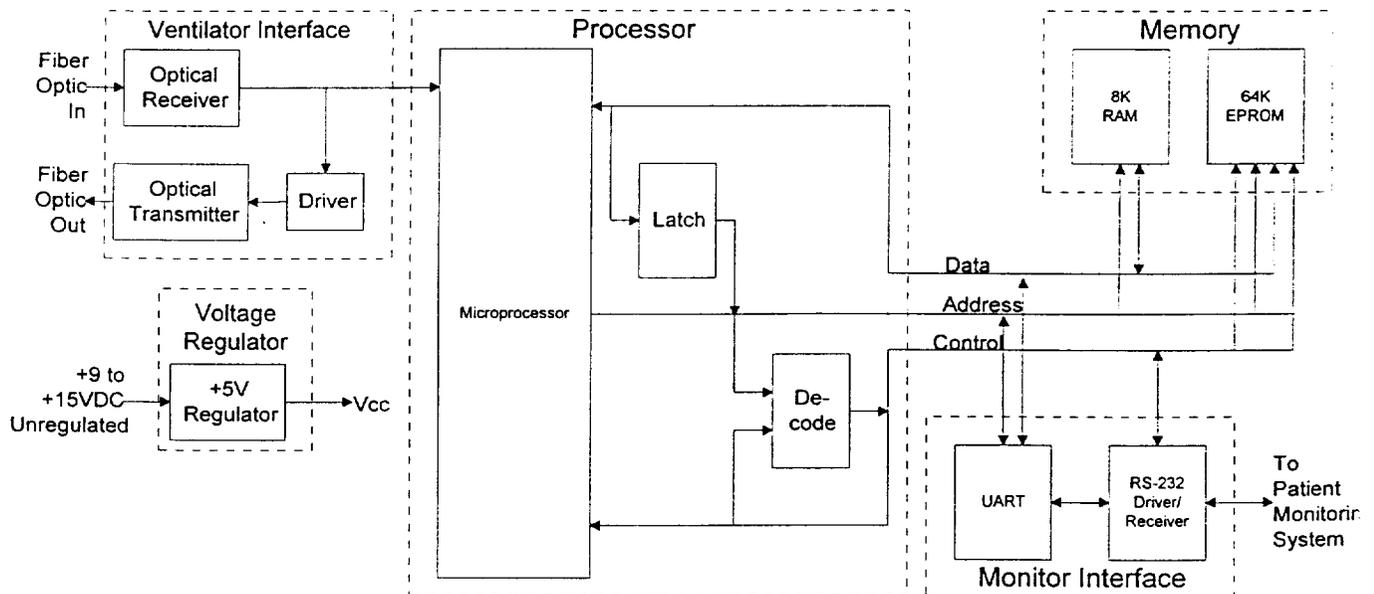


Figure 3-1
Bird Monitor Interface Installation

Serial data is received from the ventilator over the fiber optic interface. The fiber optic signal is converted to an electrical signal by a fiber optic receiver. The electrical signal then routes to a fiber optic driver for connection to an accessory device as described above.

The electrical signal also routes to the serial input of the microprocessor where the serial data is converted to parallel data. The parallel data is then stored in random access memory (RAM) for future use. Program code for the microprocessor is contained in an electrically programmable read only memory (EPROM) and is accessed as necessary for program execution.

Requests from the monitoring system are received as serial RS-232 signals. These signals are converted to logic levels by RS-232 receivers. These logic levels then are processed by a universal asynchronous receiver transmitter (UART). The UART converts the serial data to parallel data and then notifies the microprocessor by using the interrupt signal. The microprocessor reads the data from the UART, forming a request packet from the monitor. Following receipt of a complete request packet from the monitor, the processor generates the appropriate response packet from the ventilator data stored in RAM. This data is written to the UART, which converts the data to serial form. The serial data is then converted to RS-232 signals and transmitted to the monitor.



Bird Monitor Interface Block Diagram
Figure 3-2

Comparison to Predicate Device

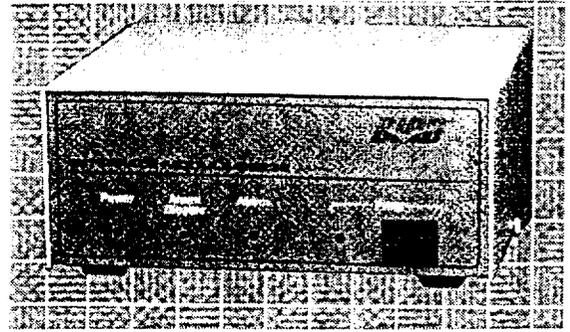
The Bird Monitor Interface™, (referred to as BMI), is a stand-alone unit providing a means of communicating information from Bird ventilators to patient monitoring systems. Specific interfaces to the Hewlett-Packard Merlin and SpaceLab's PDMS are provided, as well as, a Bird proprietary interface for use with other systems. The purpose of the Bird Monitor Interface is to deliver ventilator settings, monitored values, alarm information, and waveform data to the patient monitoring system.



Bird Monitor Interface

linking a Bird ventilator with a central computer. The means of communicating the data between the devices is a commonly used platform.

The BMI is not significantly different from the predicate device the Bird RS 232 Interface. Both devices are micro-processor controlled systems that accept the fiber optic output from the 8400STi® and V.I.P Bird® ventilators. Both interfaces act as intermediaries



RS-232 Interface Module

The development of the BMI involves four changes to the currently marketed Interface Module RS232:

1. The BMI interfaces directly with the Hewlett-Packard Merlin and SpaceLab's PDMS systems;
2. The BMI accepts input from the TBird ventilator family;
3. The BMI does not contain any alarms or indicate any alarm conditions;
4. The BMI does not interface directly to a printer

First Modification;

Direct output to the Hewlett-Packard Merlin and SpaceLabs PDMS systems.

Both the Hewlett-Packard Merlin and SpaceLab's PDMS are popular patient monitoring systems with an established hospital customer base.

Each system employs a unique, proprietary communications protocol (Hewlett-Packard VueLink and SpaceLab's Universal Flexport). The protocol, maintained and supplied by each company, describes the exact structure and hierarchy for transmitted data. Information received in the proper format can be displayed on the monitor's display screen.

The BMI functions as a data organizer for each of these monitoring systems. The Bird ventilator sends out a stream of data in a format designed by Bird. The BMI gathers this

information and structures it into the required format, one that is acceptable to the monitoring system. This does not entail substantive modification of the data. Rather, the BMI describes the data in terms that are understandable and usable by the monitoring system before sending it on.

The Data Interface-RS232 performed a similar function but formatted the data for printing or into a more universal format call the General Purpose Computer protocol. The Data Interface-RS232 could not be connected directly to a monitoring system.

Second Modification;

The BMI accepts information from the TBird family of ventilators.

The Data Interface-RS232 was designed to accept information from the 6400ST, 8400STi, and the VIP Bird. The product scope of the BMI is enhanced in comparison. The BMI can accept and transmit information from the following list of Bird ventilators: 8400STi, VIP Bird, and the TBird Series. The TBird family of ventilators use the same fiber optic output as was used in the previously listed models. All of the connections, cables, and protocols are common to the entire line.

Third Modification;

The BMI does not contain any alarms or indicate any alarm conditions.

In addition to receiving information on alarm conditions, the Data Interface-RS232 contained the means of displaying this information. The front panel of the Data Interface-RS232 housed LED indicators for an alarm condition and an alarm disable. There is an audible alarm generator located inside of the Data Interface-RS232's housing. Any of the ventilator's alarm conditions would engage the Data Interface-RS232's slave alarm system. An alarm condition would trigger a red indicator lamp and sound the audible alarm. The user could manually disable these remote alarm functions. When operating in this condition a yellow indicator lamp would be illuminated.

The BMI acts solely as a means of communicating data from the Bird ventilator to the monitoring system or hospital computer system. All alarm information and alarm conditions are relayed through the BMI to the patient monitoring system for visual and audible display by the monitoring system. The BMI does not contain any audible alarm generators or visual alarms LED indicators. The single LED indicator on the BMI indicates that a power source has been successfully attached.

Fourth Modification - The BMI does not interface directly to a printer.

The Data Interface-RS232 contained the ability to send the ventilator information to a serial printer. The user had to select the proper DIP switch position prior to activating the printer switch. A serial printer and cable were also required.

The BMI does not contain the software or hardware to interface with a printer. The information being transmitted from the BMI can only go to the specified monitoring systems or a computer.

Summary of Performance Testing

Performance testing was conducted in the laboratory to confirm input and output of data to and from the Bird Monitor Interface. Testing to Environmental, EMI/RFI and Electrical Safety Standards were performed by certified test facilities. The following table specifies all Bird Monitor Interface functions. All functions were verified to operate as designed and intended, as denoted by the checkmark.

Specification	Requirement			
BMI interface to the T-Bird, 8400STi and VIP ventilators				
<i>The following data is received from the T-Bird ventilator:</i>				
Settings	Mode	<input checked="" type="checkbox"/>	Pressure Support	<input checked="" type="checkbox"/>
	Tidal Volume	<input checked="" type="checkbox"/>	%O ₂	<input checked="" type="checkbox"/>
	Peak Flow	<input checked="" type="checkbox"/>	Pressure Control	<input checked="" type="checkbox"/>
	Breath Rate	<input checked="" type="checkbox"/>	Inspiratory Pause	<input checked="" type="checkbox"/>
	Sensitivity	<input checked="" type="checkbox"/>	Inspiratory Time	<input checked="" type="checkbox"/>
	PEEP	<input checked="" type="checkbox"/>	Waveform type	<input checked="" type="checkbox"/>
	Vol. Assured Press. Support	<input checked="" type="checkbox"/>	Low Peak Pressure Alarm	<input checked="" type="checkbox"/>
	High Pressure Limit Alarm	<input checked="" type="checkbox"/>	Low Minute Volume Alarm	<input checked="" type="checkbox"/>
Monitored Values	Flow	<input checked="" type="checkbox"/>	Mean Airway Pressure	<input checked="" type="checkbox"/>
	Proximal Pressure	<input checked="" type="checkbox"/>	Exhaled Minute Volume	<input checked="" type="checkbox"/>
	Exhaled Tidal Volume	<input checked="" type="checkbox"/>	PEEP	<input checked="" type="checkbox"/>
	Breath Rate	<input checked="" type="checkbox"/>	Inspiratory Time	<input checked="" type="checkbox"/>
	Peak Inspiratory Pressure	<input checked="" type="checkbox"/>		
Alarm Status	High Pressure Limit	<input checked="" type="checkbox"/>	Apnea	<input checked="" type="checkbox"/>
	Low Minute Volume	<input checked="" type="checkbox"/>	Low Peak Pressure	<input checked="" type="checkbox"/>
<i>The following data is received from the 8400 ventilator:</i>				
Settings	Mode	<input checked="" type="checkbox"/>	Pressure Support	<input checked="" type="checkbox"/>
	Tidal Volume	<input checked="" type="checkbox"/>	Waveform type	<input checked="" type="checkbox"/>
	Peak Flow	<input checked="" type="checkbox"/>	High Pressure Limit Alarm	<input checked="" type="checkbox"/>
	Breath Rate	<input checked="" type="checkbox"/>	Low Peak Pressure Alarm	<input checked="" type="checkbox"/>
	Sensitivity	<input checked="" type="checkbox"/>	Low Minute Volume Alarm	<input checked="" type="checkbox"/>
	PEEP	<input checked="" type="checkbox"/>	Low PEEP/CPAP Alarm	<input checked="" type="checkbox"/>
	Apnea Interval	<input checked="" type="checkbox"/>	High Breath Rate Alarm	<input checked="" type="checkbox"/>
	Back Up Breath Rate	<input checked="" type="checkbox"/>		
Monitored Values	Flow	<input checked="" type="checkbox"/>	Peak Inspiratory Pressure	<input checked="" type="checkbox"/>
	Proximal Pressure	<input checked="" type="checkbox"/>	Mean Airway Pressure	<input checked="" type="checkbox"/>
	Exhaled Tidal Volume	<input checked="" type="checkbox"/>	Exhaled Minute Volume	<input checked="" type="checkbox"/>
	Breath Rate	<input checked="" type="checkbox"/>	PEEP	<input checked="" type="checkbox"/>
	I:E Ratio	<input checked="" type="checkbox"/>	Inspiratory Time	<input checked="" type="checkbox"/>
Alarm Status	High Pressure Limit	<input checked="" type="checkbox"/>	Low Peak Pressure	<input checked="" type="checkbox"/>
	Low Minute Volume	<input checked="" type="checkbox"/>	Low PEEP/CPAP	<input checked="" type="checkbox"/>
	Apnea	<input checked="" type="checkbox"/>		
<i>The following data is received from the VIP ventilator:</i>				
Settings	Tidal Volume	<input checked="" type="checkbox"/>	Pressure Support	<input checked="" type="checkbox"/>
	Peak Flow	<input checked="" type="checkbox"/>	Termination Sensitivity	<input checked="" type="checkbox"/>
	Breath Rate	<input checked="" type="checkbox"/>	High Pressure Limit	<input checked="" type="checkbox"/>
	Sensitivity	<input checked="" type="checkbox"/>	Low Peak Pressure Alarm	<input checked="" type="checkbox"/>
	PEEP	<input checked="" type="checkbox"/>	Low PEEP/CPAP Alarm	<input checked="" type="checkbox"/>
Monitored Values	Flow	<input checked="" type="checkbox"/>	Peak Inspiratory Pressure	<input checked="" type="checkbox"/>
	Proximal Pressure	<input checked="" type="checkbox"/>	Total Breath Rate	<input checked="" type="checkbox"/>
	Exhaled Tidal Volume	<input checked="" type="checkbox"/>	Exhaled Minute Volume	<input checked="" type="checkbox"/>
	I:E Ratio	<input checked="" type="checkbox"/>	Mean Airway Pressure	<input checked="" type="checkbox"/>
	Inspiratory Time	<input checked="" type="checkbox"/>		
Alarm Status	High Pressure Limit	<input checked="" type="checkbox"/>	Low Peak Pressure	<input checked="" type="checkbox"/>
	Apnea	<input checked="" type="checkbox"/>	Low PEEP/CPAP	<input checked="" type="checkbox"/>

Specification	Requirement	<input checked="" type="checkbox"/>		
BMI interface to the Hewlett-Packard VueLink and SpaceLabs Universal Flexport				
<i>Hewlett-Packard VueLink</i>				
The following data is transmitted to the Hewlett-Packard monitor:	Total Breath Rate	<input checked="" type="checkbox"/>	Exhaled Tidal Volume	<input checked="" type="checkbox"/>
	Peak Inspiratory Pressure	<input checked="" type="checkbox"/>	Exhaled Minute Volume	<input checked="" type="checkbox"/>
	Mean Airway Pressure	<input checked="" type="checkbox"/>	Inspiratory Time	<input checked="" type="checkbox"/>
	Inspiratory Tidal Volume	<input checked="" type="checkbox"/>	PEEP/CPAP	<input checked="" type="checkbox"/>
<i>SpaceLabs Universal Flexport</i>				
The following data is transmitted to the SpaceLabs monitor:	Total Breath Rate	<input checked="" type="checkbox"/>	Exhaled Minute Volume	<input checked="" type="checkbox"/>
	Inspiratory Time	<input checked="" type="checkbox"/>	Mean Airway Pressure	<input checked="" type="checkbox"/>
	Peak Inspiratory Pressure	<input checked="" type="checkbox"/>	Exhaled Tidal Volume	<input checked="" type="checkbox"/>
	PEEP/CPAP	<input checked="" type="checkbox"/>	Inspiratory Tidal Volume	<input checked="" type="checkbox"/>
Proprietary Interface				
<i>All TBird data listed below is available through the proprietary interface.</i>				
Settings	Mode	<input checked="" type="checkbox"/>	Pressure Support	<input checked="" type="checkbox"/>
	Tidal Volume	<input checked="" type="checkbox"/>	%O2	<input checked="" type="checkbox"/>
	Peak Flow	<input checked="" type="checkbox"/>	Pressure Control	<input checked="" type="checkbox"/>
	Breath Rate	<input checked="" type="checkbox"/>	Inspiratory Pause	<input checked="" type="checkbox"/>
	Sensitivity	<input checked="" type="checkbox"/>	Inspiratory Time	<input checked="" type="checkbox"/>
	PEEP	<input checked="" type="checkbox"/>	Waveform type	<input checked="" type="checkbox"/>
	Vol. Assured Press. Support	<input checked="" type="checkbox"/>	Low Peak Pressure Alarm	<input checked="" type="checkbox"/>
	High Pressure Limit Alarm	<input checked="" type="checkbox"/>	Low Minute Volume Alarm	<input checked="" type="checkbox"/>
Monitored Values	Flow	<input checked="" type="checkbox"/>	Peak Inspiratory Pressure	<input checked="" type="checkbox"/>
	Proximal Pressure	<input checked="" type="checkbox"/>	Mean Airway Pressure	<input checked="" type="checkbox"/>
	Exhaled Tidal Volume	<input checked="" type="checkbox"/>	Exhaled Minute Volume	<input checked="" type="checkbox"/>
	Breath Rate	<input checked="" type="checkbox"/>	PEEP	<input checked="" type="checkbox"/>
	Inspiratory Time	<input checked="" type="checkbox"/>		
Alarm Status	High Pressure Limit	<input checked="" type="checkbox"/>	Apnea	<input checked="" type="checkbox"/>
	Low Minute Volume	<input checked="" type="checkbox"/>	Low Peak Pressure	<input checked="" type="checkbox"/>
<i>All 8400 data listed in below is available through the proprietary interface.</i>				
Settings	Mode	<input checked="" type="checkbox"/>	Pressure Support	<input checked="" type="checkbox"/>
	Tidal Volume	<input checked="" type="checkbox"/>	Waveform type	<input checked="" type="checkbox"/>
	Peak Flow	<input checked="" type="checkbox"/>	High Pressure Limit Alarm	<input checked="" type="checkbox"/>
	Breath Rate	<input checked="" type="checkbox"/>	Low Peak Pressure Alarm	<input checked="" type="checkbox"/>
	Sensitivity	<input checked="" type="checkbox"/>	Low Minute Volume Alarm	<input checked="" type="checkbox"/>
	PEEP	<input checked="" type="checkbox"/>	Low PEEP/CPAP Alarm	<input checked="" type="checkbox"/>
	Apnea Interval	<input checked="" type="checkbox"/>	High Breath Rate Alarm	<input checked="" type="checkbox"/>
	Back Up Breath Rate	<input checked="" type="checkbox"/>		
Monitored Values	Flow	<input checked="" type="checkbox"/>	Peak Inspiratory Pressure	<input checked="" type="checkbox"/>
	Proximal Pressure	<input checked="" type="checkbox"/>	Total Breath Rate	<input checked="" type="checkbox"/>
	Exhaled Tidal Volume	<input checked="" type="checkbox"/>	Exhaled Minute Volume	<input checked="" type="checkbox"/>
	I:E Ratio	<input checked="" type="checkbox"/>	PEEP	<input checked="" type="checkbox"/>
Alarm Status	High Pressure Limit	<input checked="" type="checkbox"/>	Low Peak Pressure	<input checked="" type="checkbox"/>
	Low Minute Volume	<input checked="" type="checkbox"/>	Low PEEP/CPAP	<input checked="" type="checkbox"/>
	Apnea	<input checked="" type="checkbox"/>	High Breath Rate	<input checked="" type="checkbox"/>
<i>All VIP data listed below is available through the proprietary interface.</i>				
Settings	Mode	<input checked="" type="checkbox"/>	PEEP	<input checked="" type="checkbox"/>
	Tidal Volume	<input checked="" type="checkbox"/>	Pressure Support	<input checked="" type="checkbox"/>
	Peak Flow	<input checked="" type="checkbox"/>	High Pressure Limit	<input checked="" type="checkbox"/>
	Breath Rate	<input checked="" type="checkbox"/>	Low Peak Pressure Alarm	<input checked="" type="checkbox"/>
	Sensitivity	<input checked="" type="checkbox"/>	Low PEEP/CPAP Alarm	<input checked="" type="checkbox"/>
Monitored Values	Flow	<input checked="" type="checkbox"/>	Peak Inspiratory Pressure	<input checked="" type="checkbox"/>
	Proximal Pressure	<input checked="" type="checkbox"/>	Total Breath Rate	<input checked="" type="checkbox"/>
	Exhaled Tidal Volume	<input checked="" type="checkbox"/>	Exhaled Minute Volume	<input checked="" type="checkbox"/>
	I:E Ratio	<input checked="" type="checkbox"/>		
Alarm Status	High Pressure Limit	<input checked="" type="checkbox"/>	Low Peak Pressure	<input checked="" type="checkbox"/>
	Apnea	<input checked="" type="checkbox"/>	Low PEEP/CPAP	<input checked="" type="checkbox"/>

Specification	Requirement	
Power On Self Test	Runs at power application	<input checked="" type="checkbox"/>
	verifies EPROM operation	<input checked="" type="checkbox"/>
	verifies processor operation	<input checked="" type="checkbox"/>
Electrical Requirements		
Electrical Safety	IEC601-1:1988	<input checked="" type="checkbox"/>
Dielectric Withstand	IEC 601-1:1988, clause 20	<input checked="" type="checkbox"/>
AC Power Grounding and Polarity	output cable, connector cannot be reversed	<input checked="" type="checkbox"/>
	reverse polarity will not damage the BMI	<input checked="" type="checkbox"/>
Leakage Current	In accordance with IEC601-1, 1988	<input checked="" type="checkbox"/>
Electromagnetic Compatibility		
<i>Emissions</i>	IEC 601-1-2	<input checked="" type="checkbox"/>
Radiated and Conducted EMI	In accordance with CISPR11	<input checked="" type="checkbox"/>
Magnetic Fields	In accordance with MIL-5TD462D, RE101	<input checked="" type="checkbox"/>
<i>Immunity</i>	IEC 601-1-2	<input checked="" type="checkbox"/>
Electrostatic Discharge	In accordance with IEC801-2, FDA	<input checked="" type="checkbox"/>
Radiated Electromagnetic Fields	FDA Reviewer's Guidance	<input checked="" type="checkbox"/>
<i>Fluctuations, Transients, Surges</i>		
Steady State Voltage	120VAC +10%,-20%	<input checked="" type="checkbox"/>
Dropout	FDA Reviewer's Guidance	<input checked="" type="checkbox"/>
Slow Sags and Surges	FDA Reviewer's Guidance	<input checked="" type="checkbox"/>
Fast Transient Bursts	IEC801-4 for table top equipment	<input checked="" type="checkbox"/>
Fast Surges	FDA Reviewer's Guidance	<input checked="" type="checkbox"/>
<i>Conducted EMC</i>	In accordance with MIL-5TD461 D	<input checked="" type="checkbox"/>
<i>Magnetic Fields</i>	In accordance with RS10I of MIL-5TD462D	<input checked="" type="checkbox"/>
<i>Quasi-Static Electric Fields</i>	FDA Reviewer's Guidance	<input checked="" type="checkbox"/>
Mechanical and Environmental Requirements		
Shock	In accordance with IEC 68-2-27	<input checked="" type="checkbox"/>
Sinusoidal Vibration	In accordance with IEC 68-2-6	<input checked="" type="checkbox"/>
Random Vibration	In accordance with IEC 68-2-34	<input checked="" type="checkbox"/>
Fluid Spill Resistance	In accordance with IEC 601-1, Clause 44.6	<input checked="" type="checkbox"/>
Operating Temperature	+10 to +40°C, 30 to 75% RH	<input checked="" type="checkbox"/>
Storage Temperature	-20 to +60°C, up to 95% RH	<input checked="" type="checkbox"/>
Surface Temperature	Less than 41 °C while in an ambient of 35°C	<input checked="" type="checkbox"/>

Hardware and software performance testing verified that the Bird Monitor Interface meets all of its performance requirements and that this device is substantially equivalent to medical devices currently legally marketed in the United States.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 22 1998

Mr. Neil Battiste
Bird Products Corporation
1100 Bird Center Drive
Palm Springs, CA 92262-8099

Re: K982580
Bird Monitor Interface
Regulatory Class: II (two)
Product Code: 73 CBK
Dated: July 22 1998
Received: July 24, 1998

Dear Mr. Battiste:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

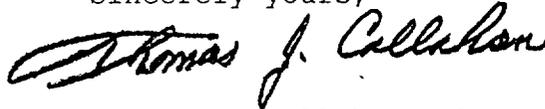
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Mr. Neil Battiste

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink that reads "Thomas J. Callahan". The signature is written in a cursive style with a large, prominent initial "T".

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

The Bird Monitor Interface (BMI) is a stand-alone unit providing a means of communicating information from Bird ventilators to patient monitoring systems. Specific interfaces to the Hewlett-Packard Merlin and SpaceLabs PDMS are provided, as well as a Bird proprietary interface for use with other systems. The purpose of BMI is to deliver ventilator settings, monitored values, alarm information and waveform data to the patient monitoring system.

Mark Kramer
(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K982580